**SERIAL NO.** 09/738,742

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## **U.S. PATENT DOCUMENTS**

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GROUP Not-ussigned

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER | DATE       | NAME            | CLASS | SUBCLASS | FILING DATE<br>IF<br>APPROPRIATE |
|---------------------|--------------------|------------|-----------------|-------|----------|----------------------------------|
| JAZ.                | RE 32,310          | 12/16/1986 | Debono          | 530   | 317      |                                  |
|                     | RE 32,311          | 12/16/1986 | Debono          | 530   | 317      |                                  |
|                     | 4,396,543          | 08/02/1983 | Debono          | 260   | 112.5R   | •                                |
|                     | 4,399,067          | 08/16/1983 | Debono          | 260   | 112.5R   |                                  |
| <u> </u>            | 4,482,487          | 11/13/1984 | Abbott et al.   | 260   | 112.5R   |                                  |
|                     | 4,524,135          | 06/18/1985 | Abbott et al.   | 435   | 69       |                                  |
|                     | 4,537,717          | 08/27/1985 | Abbott et al.   | 260   | 112.5R   |                                  |
|                     | 5,573,936          | 11/12/1996 | Kreuzman et al. | 435   | 196      |                                  |
|                     | 5,629,288          | 05/13/1997 | Lattrell et al. | 514   | 9        |                                  |
| -07<br>-            | 5,912,226          | 06/15/1999 | Baker et al.    | 514   | 9        |                                  |

## FOREIGN PATENT DOCUMENTS

| EXAMINER | DOCUMENT NUMBER | DATE       | COLINTEN | 01.400 | CURCI ACC | TRANSLATION |    |
|----------|-----------------|------------|----------|--------|-----------|-------------|----|
| <u> </u> | DOCUMENT NUMBER | DATE       | COUNTRY  | CLASS  | SUBCLASS  | YES         | NO |
| 19 CV    | 0 885 957 A1    | 12/23/1998 | EP       |        |           |             |    |
| ZZ.      | WO 99/43700     | 9/2/1999   | РСТ      |        |           |             |    |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| EXAMINER INITIAL |   |
|------------------|---|
| IX.              | Alborn, W. E. Jr. et al., "Daptomycin Disrupts Membrane Potential in Growing Staphylococcus aureus," Antimicrobial Agents and Chemotherapy 35: 2282-2287 (1991).        |
| DL.              | Allen, N. E. et al. "Inhibition of Peptidoglycan Biosynthesis in Gram-Positive Bacteria by LY146032," Antimicrobial Agents and Chemotherapy 31: 1093-1099 (1987).       |
| DZ'              | Allen, N. E. et al. "Inhibition of Membrane Potential-Dependent Amino Acid Transport by Daptomycin," <i>Antimicrobial Agents and Chemotherapy</i> 35: 2639-2642 (1991). |
| SZ.              | Baltz, R. H., "Lipopeptide Antibiotics Produced by Streptomyces roseosporus and Streptomyces fradiae," in Biotechnology of Antibiotics, 2d Ed., 415-435 (1997).         |

**EXAMINER** 

DATE CONSIDERED 10/16/02

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

| FORM PTD-1949                       | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO. SERIAL NO. 09/738,742 |                       |  |  |
|-------------------------------------|---|--|-----------------------|--|--|
| APR 0 2 2001 ENFORMATION DISCLOSURE |   | APPLICANTS Jason Hill et al.           |                       |  |  |
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) **EXAMINER** INITIAL Bingen, E. et al. "Bactericidal Activity of Daptomycin Against Vancomycin-Resistant Enterococcus faecium in an in Vitro Pharmacokinetic Model," Eur. J. Clin. Microbiol. Infect. Dis. 10: 1062-1065 (1991). Boeck, LaVerne D. et al. "Deacylation of A21978C, An Acidic Lipopeptide Antibiotic Complex, by Actinoplanes utahensis," Journal of Antibiotics XLI: 1085-1092 (1988). Boeck, L. D. et al. "A54145, A New Lipopeptide Antibiotic Complex: Discovery, Taxonomy, Fermentation and HPLC," Journal of Antibiotics XLIII: 587-593 (1990). Champlin, Franklin R. et al. "Cell Envelope Impermeability to Daptomycin in *Pseudomonas* aeruginosa and Pasteurella multocida," Current Microbiology 21: 367-372 (1990). Chong, Pei Pei et al. "Physical Identification of a Chromosomal Locus Encoding Biosynthetic Genes for the Lipopeptide Calcium-Dependent Antibiotic (CDA) of Streptomyces coelicolor A3(2)," Microbiology 144: 193-199 (1998). Debono, M. et al. "A21978C, A Complex of New Acidic Peptide Antibiotics: Isolation, Chemistry, and Mass Spectral Structure Elucidation," Journal of Antibiotics XL: 761-777 (1987).Debono, M. et al. "Enzymatic and Chemical Modifications of Lipopeptide Antibiotic A21978C: The Synthesis and Evaluation of Daptomycin (LY146032)," Journal of Antibiotics XLI: 1093-1105 (1988). Debono, M. et al. "Synthesis of New Analogs of Echinocandin B by Enzymatic Deacylation and Chemical Reacylation of the Echinocandin B Peptide: Synthesis of the Antifungal Agent Cilofungin (LY121019)," Journal of Antibiotics XLII: 389-397 (1989). Dong, Mei-Yan et al. "Treatment of Clostridium difficile Colitis in Hamsters with a Lipopeptide Antibiotic, LY146032," Antimicrobial Agents and Chemotherapy 31: 1135-1136 (1987)Eid, Pascale et al. "Effect of Daptomycin on the Barotropic Behavior of Dioleoylphosphatidylglycerol: An Infrared Spectroscopic Investigation," Chemistry and Physics of Lipids 83: 131-140 (1996).

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APPLICANTS

Jason Hill et al.

FILING DATE 12/15/2000 GROUP Not assigned

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| EXAMINER INITIAL |  |
|------------------|--|
| Dir.             | Eliopoulos, George M. et al. "In Vitro Activity and Mechanism of Action of A21978C <sub>1</sub> , a Novel Cyclic Lipopeptide Antibiotic," <i>Antimicrobial Agents and Chemotherapy</i> 27: 357-362 (1985).       |
| DY.              | Huber, F. M. et al. "The Formation of Daptomycin by Supplying Decanoic Acid to<br>Streptomyces roseosporus Cultures Producing the Antibiotic Complex A21978C," Journal of<br>Biotechnology 7: 283-292 (1988).    |
|                  | Huber, F. M. et al. "The Synthesis of A21978C Analogs by Streptomyces roseosporus Cultivated Under Carbon Limitation and Fed Fatty Acids," Biotechnology Letters 12: 789-792 (1990).                             |
| Del.             | Inokoshi, Junji et al. "Cloning and Sequencing of the Aculeacin A Acylase-Encoding Gene From Actinoplanes utahensis and Expression in Streptomyces lividans," Gene 119: 29-35 (1992).                            |
| DL.              | Inokoshi, Junji et al. "Efficient Production of Aculeacin A Acylase in Recombinant Streptomyces strains," Appl. Microbiol. Biotechnol. 39: 532-536 (1993).   |
| Ox,              | Kempter, Christoph et al. "CDA: Calcium-Dependent Peptide Antibiotics from Streptomyces coelicolor A3(2) Containing Unusual Residues," Angew. Chem. Int. Ed. Engl. 36: 498-501 (1997).                           |
| W.               | Kirsch, Lee E. et al. "Kinetics of the Aspartyl Transpeptidation of Daptomycin, a Novel Lipopeptide Antibiotic," <i>Pharmaceutical Research</i> 6: 387-393 (1989).   |
|                  | Lakey, Jeremy H. et al. "The Role of Acyl Chain Character and Other Determinants on the Bilayer Activity of A21978C An Acidic Lipopeptide Antibiotic," <i>Biochimica et Biophysica Acta</i> 859: 219-226 (1986). |
| DZ.              | Lakey, Jeremy H. et al. "Fluorescence Indicates a Calcium-Dependent Interaction Between the Lipopeptide Antibiotic LY146032 and Phospholipid Membranes," <i>Biochemistry</i> 27: 4639-4645 (1988).               |
|                  | Lakey, Jeremy H. et al. "The Lipopeptide Antibiotic A21978C Has a Specific Interaction With DMPC Only in the Presence of Calcium Ions," <i>Biochimica et Biophysica Acta</i> 985: 60-66 (1989).                  |

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vid Letton

DATE CONSIDERED () //6

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

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| CUB-4                           | 09/738,742   |
| APPLICANTS<br>Jason Hill et al. |              |
| FILING DATE                     | GROUP        |
| 12/15/2000                      | Not assigned |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| EXAMINER INITIAL                   |  |
|------------------------------------|--|
| De C                               | Lee, Belle L. et al. "Effect of Protein Binding of Daptomycin on MIC and Antibacterial Activity," <i>Antimicrobial Agents and Chemotherapy</i> 35: 2505-2508 (1991).   |
| DL.                                | Liebowitz, Lynne D. et al. "In Vitro Selection of Bacteria Resistant to LY146032, a New Cyclic Lipopeptide," Antimicrobial Agents and Chemotherapy 32: 24-26 (1988).   |
| DZ                                 | Maget-Dana, Régine et al. "A Comparative Monomolecular Film Study of Antibiotic A21978C Homologues of Various Lipid Chain Length," <i>Biochimica et Biophysica Acta</i> 962: 201-207 (1988).                                     |
| $\mathscr{D}\!\mathcal{L}_{\iota}$ | Zambias, Robert A. et al. "Preparation and Structure-Activity Relationships of Simplified Analogues of the Antifungal Agent Cilofungin: A Total Synthesis Approach," <i>Journal of Medicinal Chemistry</i> 35: 2843-2855 (1992). |
| SK,                                | Zmijewski, M.J. et al. "Role of Branched Chain Fatty Acid Precursors in Regulating Factor Profile in the Biosynthesis of A21978 C Complex," <i>Journal of Antibiotics</i> XXXIX: 1483-1485 (1986).                               |

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DATE CONSIDERED

10/16/02